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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,920	09/19/2001	Sridhar Ramaswamy	2825.2020-002	9860

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,920

Applicant(s)

RAMASWAMY ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 76-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 84-92 is/are allowed.
- 6) ☒ Claim(s) 1 and 76-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/30/03, 6/4/04, 9/30/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. The denial of priority to Provisional Application Nos. 60/233, 534 and 60/278,749 in the Office action mailed 31 March 2005 is withdrawn because accession numbers do not appear in the instant claims.

Specification

2. The use of the trademark AFFYMETRIX and GENBANK has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. The objection to claim 1, 5, and 76-83 in the Office action mailed 31 March 2005 for failing to be limited to the elected invention is withdrawn in view of the amendment to the claims filed 30 September 2005.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 5, and 76-83 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement in the Office action mailed 31 March 2005 is withdrawn in view of the arguments presented by the applicants in pages 5-6 of the response filed 30 September 2005.

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5. The rejection of claims 1, 5, and 76-83 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement in the Office action mailed 31 March 2005 is withdrawn in view of the arguments presented by the applicants in pages 6-8 of their response filed 30 September 2005, and because disclosed accession numbers in the specification are not claimed and are not essential subject matter.

Claims Rejected Under 35 U.S.C. § 102

6. The rejection of claims 1, 5, and 76-83 under 35 U.S.C. § 102(e) as being anticipated by Horne et al. (U.S. 2002/0142981 A1) or Williams et al. (U.S. 2004/0033502 A1) in the Office action mailed 31 March 2005 is withdrawn in view of the amendment to the claims and the arguments presented by the applicants in page 9 of the response filed 30 September 2005.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 1 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechreche et al. (reference CB in the information disclosure statement filed 30 September 2005).

The claims are drawn to a method of identification of colorectal tumor tissue comprising measuring the expression level of the galectin-4 gene in a sample and comparing the level to that of a known colorectal tumor expression level. In some embodiments the method uses DNA or RNA and hybridization probes.

Rechreche et al. shows in the abstract and particularly in figures 4 and 5 that galectin-4 is underexpressed in human colorectal tumor samples relative to normal colonic mucosa tissue. Rechreche et al. shows on page 225 that galectins are a class of vertebrate lectin proteins that bind galactosides. Rechreche et al shows in figure 4 that cDNA probes specific for galectin-4 were hybridized to RNA from tissue samples. Rechreche et al. concludes on page 229 that measurement of reduced galectin-4 expression levels is a potential marker of colorectal carcinogenesis. Rechreche et al. does not show identification of a tissue sample as a colorectal tumor sample by measurement of its level of galectin-4 expression relative to known colorectal tumor sample galectin-4 expression levels.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the assay of galectin-4 levels in colorectal samples of Rechreche et al. to identify colorectal tumors because Rechreche et al. shows that low levels of galectin-4 expression levels in a colorectal tissue sample (relative to normal colorectal mucosa expression levels) correlate well with the tissue sample being a colorectal tumor.

10. Claims 1, 76, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechreche et al. as applied to claims 1 and 76-79 above, and further in view of Golub et al.

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The claims are drawn to a method of identification of colorectal tumor tissue comprising measuring the expression level of the galectin-4 gene in a sample and comparing the level to that of a known colorectal tumor expression level that utilizes oligonucleotide microarrays.

Rechreche et al. as applied to claims 1 and 76-79 above do not show use of oligonucleotide microarrays.

Golub et al. shows in the abstract a method of classifying leukemia cells to known classes by measurement of gene expression levels of 50 genes that were found to be predictive of leukemia class (see figure 3). Golub et al. shows at the bottom of the third column on page 531 that a high density oligonucleotide microarray comprising 6,817 human gene probes was used to assay gene expression.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rechreche et al. by measuring expression levels of galectin-4 by use of an oligonucleotide microarray such as used by Golub et al. because Golub et al. shows that oligonucleotide microarrays are useful to measure multiple gene expression levels of cancerous cells, and that many different gene expression levels are relevant to cancer diagnostics.

11. Claims 1, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechreche et al. as applied to claims 1 and 76-79 above, and further in view of Lotan et al.

The claims are drawn to a method of identification of colorectal tumor tissue comprising measuring the expression level of the galectin-4 gene in a sample and comparing the level to that of a known colorectal tumor expression level that utilizes antibodies.

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Rechreche et al. as applied to claims 1 and 76-79 above does not use antibodies to measure expression levels of galectin-4.

Lotan et al. shows general methods of isolating antibodies specific for lectins on pages 49-50. Lotan shows measurement of lectins in human colorectal carcinoma tissue by use of antibodies specific for the lectins (see figures 2-4). Lotan et al. conclude on page 55 that levels of L-31 lectin measured by their antibody method correlate with colorectal cancer progression.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure the galactin-4 levels of colorectal samples of Rechreche et al. by use of the antibody procedure of Lotan et al. because Rechreche et al. show that measurement of expression levels of the lectin galectin-4 correlate with colorectal tumors and Lotan et al. shows a method of measurement of lectin expression levels by use of antibodies that correlates with colorectal tumors.

Allowable Subject Matter

12. Claims 84-92 are allowed.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 23 December 2005

John S. Brusca
Primary Examiner
Art Unit 1631

jsb